Dkt. 61248-A/JPW/BJA

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants

Animune Inc.

U.S. Serial No

09/776,010

Filed

February 2, 2001

For

HUMAN HERPESVIRUS 6A AND 6B TRANSFER FACTORS FOR THE TREATMENT OF CHRONIC FATIGUE SYNDROME AND MULTIPLE SCLEROSIS FATIGUE

1185 Avenue Of The Americas New York, New York 10036 May 15, 2001

Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

TRANSMITTAL OF VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS UNDER 37 C.F.R. §1.9(f) AND §1.27(d) AND DECLARATION AND POWER OF

ATTORNEY

Assignee submits herewith a Verified Statement (Declaration) Claiming Small Entity Status Under 37 C.F.R. §1.9(f) and §1.27(d) as Exhibit A. This Verified Statement is signed by R. Riley Shuler, the authorized official of the assignee, Animune Inc.

Applicants also submit as Exhibit B a Declaration and Power of Attorney pursuant to 37 C.F.R. §1.53(f) and in compliance with 37 C.F.R. §1.63. The Declaration refers to the application's above-identified serial number and filing date.

No fee is deemed necessary in connection with the filing of this Communication. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents

. White No. 28,678

John P. White Registration No. 28,678 Attorney for Applicants Cooper & Dunham LLP 1185 Avenue of the Armericas New York, New York 1 0036 (212) 278-0400

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SMALL ENT	TITY STATUS UNDER 37 C.F.R	. \$1.9(£)
AND \$1	.27 (C) - SMALL BUSINESS CO	ONCERN
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hereby declare that I am:		•
X the owner of the si	mall business concern iden	
-ssignal of the	emall husiness concern empo	owered to act on behalf of th
concern identified	below:	
Coucet !! Tourstille		
ame of Concern: Animune	Inc	
ddress of Concern: 1236 Gin	Bay Road	
Cameron,	SC 29030	
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anore: Separat verified statements are required for each named person, conc rn, or organization having rights to the invintion averring to their status as small

- (c) An independent inventor as us d in this chapter means any inventor who (1) has not assign d, grant d, conveyed, or licensed, and (2) is under no obligation under contract or law t assign, grant, convey, or license, any rights in the invention to any person who could not likewis be classified as an independent inventor if that person had made the invention, or to any concern which would not qualify as a small business concern or a nonprofit organization under this section.
- (d) A small business concern as used in this chapter means any business concern as defined by the Small Business Administration in 13 C.P.R. §121.3-18, published on Sept mber 30, 1982 at 47 FR 43273. For the convenience of the users of these regulations, that definition states:
- \$121.3-18 Definition of small business for paying reduced patent fees under Title 35, U.S. Code.
- (a) Pursuant to Pub. L. 97-247, a small business concern for purposes of paying reduced fees under 35 U.S. Code 41(a) and (b) to the Patent and Trademark Office means any business concern (1) whose number of employees, including those of its affiliates, does not exceed 500 persons and (2) which has not assigned, grantes, convy d, or licensed, and is under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor if that person had made the invention, or to any concern which would not qualify as a small business concern or a nonprofit organization under this section. For the purpose of this section concerns are affiliates of each other when either, directly or indirectly, one concern controls repower to control the other, or a third party or parties controls or has the power to control both. The number of employees of the business concern is the average over the fiscal year of the the persons employed during each of the pay periods of the fiscal year. Employees are those persons employed on a full-time, part-time remporary basis during the previous fiscal year of the concern.
- (b) If the Patent and Trademark Office determines that a concern is not eligible as a small business concern within this section, the concern shall have a right to appeal that d termination to the Small Business Administration. The Patent and Trademark Office shall transmit its written decision and the pertinent size determination fil the SBA in the event of such adverse determination and size appeal. Such appeals by concerns should be submitted to the SBA at 1441 L Street, NW., Washington, D.C. 20416 (Attention: SBA Office of General Counsel). The appeal should state the basis upon which it is claimed that the Patent and Trademark Office initial size determination on the concern was in error; and the facts and arguments supporting the concern's claimed status as a small business concern under this section.
- (e) A nonprofit organization as used in this chapter means (1) a university or other institution of higher education located in any country; (2) an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c)(3)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)); (3) any nonprofit scientific or educational organization qualified under a nonprofit organization statute of a state of this country (35 U.S.C. 201(i)); or (4) any nonprofit organization located in a foreign country which would qualify as a nonprofit organization under paragraphs (e) (2) or (3) of this scient if it were located in this country.

Small Entity/Small Business Concern

Page -2-

Applicant: Animune Inc. Serial No.: 09/776,010 Filed: February 2, 2001

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any main tenance fee due after the date on which status as a small entity is no longer appropriate. 37 C.F.R. §1.28(b) *.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Name of Person Signing:	Dr. R. Riley Shuler		
Title In Organization:	President	·	
Address:	1236 Gin Bay Road		
Address.	Cameron, SC 29030		· · · · · · · · · · · · · · · · · · ·
Signature: RRJe	y Shuler worn		
Date Of Signature:	4-26-2001		
Date 01 D23			

(b) Once status as a small entity has been established in an application or patent, fees as a small entity may thereafter be paid in that application or patent without regard to a change in status until the issue fee is due or any maintenance fee is due. Notification of any change in status resulting in loss of entitlement to small entity status must be filed in the application or patent prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate pursuant to \$1.9 of this part. The notification of change in status may be signed by the applicant, any person authorized to sign on behalf of the assignee, or an attorney or agent of record or acting in a representative capacity pursuant to \$1.34(a) of this part.



As a below-named inventor, I hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

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hereby claim foreign price 65(b) of any foreign application application application along the following the following application applicat	pplication(s) for pate n which designated c ified helow any forets	ni or invenior's certific at least one country of annlication for patel	cale, or Section ther than the U nt or inventor's	Inited States. It certificate, Or i
Prior Foreign Application(s)		Priority Claimed		
rior Foreign Application				
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rior Foreign Application <u>Number</u> N/A	Country.	Filing Date	<u>Yes</u>	<u>No</u>
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Applicants: Gregory B. Wi on et al

U.S. Serial No.: 09/776,0

Filed: February 2, 2001

Page 2

Declaration	and Pa	ower of	Attorney
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I hereby claim the benefit under Title 35. United States Code. Section 119(e) of any United States provisional application(s) listed below:

Provisional Application No.	Filing Date	<u>Status</u>	
60/179,647	February 2, 2000	Pending as of Februa	ry 2, 200
·			

I hereby claim the benefit under Title 35. United States Code, Section 120 of any United States Application(s). or Section 365(c) of any PCT International Application(s) designating the United States listed below. Insofar as this application discloses and claims subject matter in addition to that disclosed in any such prior Application in the manner provided by the first paragraph of Title 35. United States Code. Section 112. I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56, which became available between the filing date(s) of such prior Application(s) and the national or PCT international filing date of this application:

Application Serial No.	Filing Date	<u>Status</u> .
n/A		

And I hereby appoint

John P. White (Reg. No. 28,678); Christopher C. Dunham (Reg. No. 22,031); Norman H. Zivin (Reg. No. 25,385); Jay H. Maioli (Reg. No. 27,213); William E. Pelton (Reg. No. 25,702); Robert D. Katz (Reg. No. 30,141); Peter J. Philips (Reg. No. 29,691); Wendy E. Miller (Reg No. 35,615); Richard S. Milner (Reg. No. 33,970); Robert T. Maldonado (Reg. No. 38,232); Paul Teng (Reg. No. 40,837); Richard F. Jaworski (Reg. No. 33,515); Pedro C. Fernandez (Reg. No. 41,741); Gary J. Gershik (Reg. No. 39,992); Jane M. Love (Reg. No. 42,812); Spencer H. Schneider (Reg. No. 45,923); and Raymond A. Diperna (Reg. No. 44,063)

and each of them. all c/o Cooper & Dunham LLP. 1185 Avenue of the Americas, New Y rk New York 10036, my altorneys, each with full power of substitution and revocation, to prosecute this application, to make alterations and amendments therein, to receive the patent, to transact all business in the Pasent and Trademark Office connected therewith and to file any International Applications which are based thereon under the provisions of the Patent Cooperation Treaty.

Applicants: Gregory B. son et al

U.S. Serial No.: 09/776 Filed: February 2, 2001

	I Daniel	of Attorney
Declaration	ana Power	0) 11

Page 3

Please address all communications, and direct all telephone calls, regarding this application to:

John P. White

Cooper & Dunham LLP

1185 Avenue of the Americas

New York, New York 10036

Tel. (212) 278-0400

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true: and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, the knowledge that willful false statements and the United States Code and that such willful false statements or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Reg. No. 28,678

Full name of sole or	Gregory Bruce Wils	on			<u> </u>	
first joint inventor	Shall)				·	·
Inventor's signature_	JAN PIN	5		4-27-	2001	
Citizenship U.S.		_Date of signati	ure			
Residence_ United	States					
Post Office Address	412 Beckenham Lane	Greenville	_Sout	h_Carol	ina 2960	19
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Full name of joint inventor (if any) R.	Riley Shuler					·
Inventor's signature	Riley Shuler R Rily Sh	uler		·		
Citizenship U.S.		_Date of signa	ture	4-2	6-20	0/
Residence United	States		<u> </u>			· ·
Post Office Address	1236 Gin Bay Road	. Cameron. S	South	Carolina	2903	0
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Full name of joint inventor (if any)						
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Inventor's signature	:	Date of signal	rure		· · · · · · · · · · · · · · · · · · ·	· ·
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